DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date . JAN 31 1997

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of CIBA Vision Corporation's Unizyme™ Enzymatic Cleaner - ACTION

To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved ___ Disapproved ___ Date _____

Prepared by Myra Smith, CDRH, HFZ-460, December 17, 1996, 594-1744

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DRAFT

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. _____]

CIBA VISION CORP.; PREMARKET APPROVAL OF UNIZYME™ ENZYMATIC CLEANER

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by CIBA Vision Corp., Duluth, GA, for premarket approval, under section 515 of the Federal Food, Drug, and Cosmetic Act (the act), of Unizyme™ Enzymatic Cleaner. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on January 31, 1997, of the approval of the application.

DATE: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

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FOR FURTHER INFORMATION CONTACT:

James F. Saviola, O.D.,

Center for Devices and Radiological Health (HFZ-460),

Food and Drug Administration,

9200 Corporate Blvd.,

Rockville, MD 20850,

301-594-1744.

SUPPLEMENTARY INFORMATION: On August 15, 1996, CIBA Vision Corp., Duluth, GA, 30155-1518 submitted to CDRH an application for premarket approval of the Unizyme™ Enzymatic Cleaner. The device is a periodic cleaner and is indicated for use with chemical (including hydrogen peroxide) lens care systems in the weekly cleaning of soft (hydrophilic) contact lenses (including daily wear, extended wear, tinted lenses, and lenses prescribed for scheduled replacement).

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

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On January 31, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity For Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under §10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition

supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

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This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.

_____

B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 1997

Mr. Steven Dowdley
Senior Associate, Regulatory Affairs
CIBA Vision Corporation
Product Registration
11460 John Creek Parkway
Duluth, GA 30155-1518

Re: P960024
Unizyme™ Enzymatic Cleaner
Filed: August 15, 1996
Amended: October 1, November 27, and December 5 and 12, 1996

Dear Mr. Dowdley:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Unizyme™ Enzymatic Cleaner. This device is indicated for use with chemical (including hydrogen peroxide) lens care systems in the weekly cleaning of soft (hydrophilic) contact lenses (including daily wear, extended wear, tinted lenses and lenses prescribed for scheduled replacement). We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

Expiration dating for this device has been established and approved at 18 months for the individually sealed, blister package tablets which are supplied in packages of 2 and 12 tablets. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

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Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ms. Myra Smith or James F. Saviola, O.D., at (301) 594-1744.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant**(s)** involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

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(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

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REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 240
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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Summary of Safety and Effectiveness

I. General Information

A. Premarket Approval Application (PMA) Number: P960024
Date Filed: August 15, 1996
Date Approved: JAN 31 1997

B. Device Generic Name: periodic cleaner

C. Device Trade Name: Unizyme™ Enzymatic Cleaner

D. Applicant's Name and Address: CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, GA 30155-1518

E. Good Manufacturing Practice (GMP) Inspection:

Conclusion: The manufacturing site was found to be in compliance with device GMP requirements.

II. Indications

Unizyme™ Enzymatic Cleaner is indicated for use with chemical (including hydrogen peroxide) lens care systems in the weekly cleaning of soft (hydrophilic) contact lenses (including daily wear, extended wear, tinted lenses and lenses prescribed for scheduled replacement).

III. Summary

The device has been marketed internationally since 1994. The countries in which the device is currently marketed are Austria, Belgium, Canada, Chile, Equador, France, Germany, Luxemburg, Netherlands, and the United Kingdom. The device has not been withdrawn from marketing in any country.

The applicant performed non-clinical and clinical testing on the device in accordance with the FDA Testing Guidelines for Class III Soft (Hydrophilic) Contact Lens Solutions dated July 1985 and a preliminary June 1995 Draft Premarket Notification Document for Contact Lens Care Products. The non-clinical testing supports the safety and effectiveness of the device from microbiology, toxicology, chemistry and manufacturing perspectives. Data were presented from a randomized, double-masked, parallel group clinical trial consisting of 48 eyes in the Test Group using the subject device and 24 eyes in a Control Group using a currently marketed enzymatic cleaner.

The subjects in both groups were followed for one month and clinically evaluated. The Test Group included 9 males and 15 females and the Control Group included 5 males and 7 females which is representative of the contact lens wearing population in the United States. Based on the detailed analysis of the data presented in the PMA, it was determined that the clinical findings for the Control Group and Test Group, i.e., adverse reactions, positive slit lamp findings, patient symptoms, problems and complaints, visual acuity, lens replacements, discontinued patients, and lens wearing time were similar and within expected limits for soft (hydrophilic) contact lens wearers. Any differences between the Control Group and the Test Group do not raise concerns about the safety and effectiveness of the device when accompanied by appropriate labeling. Although the potential exists for minor differences in physiological response by gender for the target population, the minimal number of clinically significant findings does not indicate gender difference to be of clinical importance for this device.

IV. Safety and Effectiveness Data

A. Non-clinical Data

The applicant conducted a battery of in-vivo and in-vitro acute toxicology studies that support the safety and biocompatibility of the solution with soft (hydrophilic) contact lens materials. Additionally, chemistry and manufacturing information was submitted demonstrating that the enzyme tablet is suitable for use with chemical (including hydrogen peroxide) lens care systems in the weekly cleaning of soft (hydrophilic) contact lenses (including daily wear, extended wear, tinted lenses and lenses prescribed for scheduled replacement). The adequacy of the manufacturing process, including shelf-life expiration dating, was established through a review of the manufacturing and microbiology data submitted in the PMA as well as through an on-site GMP inspection.

B. Clinical Data (Test Group)

Accountability (48 eyes enrolled): 48 completed

Visual Acuity:	Initial Visit with Lens	Final Visit with Lens
20/30 or better	46	45
20/40 or worse	2	3

Wear Time:	Initial	Final (1 month)
Daily	13 hours	13 hours

Adverse Reactions: None reported for all eyes enrolled

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Slit Lamp Findings*:	Initial Visit (78/48 eyes)=162.5%	Final Visit (67/48 eyes)=139.6%
Neovascularization	20	20
Staining	32	25
Injection	8	7
Tarsal Abnormalities	16	13
Other	2	2

*Multiple Findings Reported

Symptoms, Problems, Complaints: (65 reports/144 exams)= 45.1%
Categories reported = 10

Vision Related (e.g. , blurred, variable vision)	(22/65) = 33.8%
Comfort (e.g. discomfort, itching)	(32/65) = 49.2%
Other (e.g., lens needs cleaning)	(11/65) = 16.9%

Lens Replacements: (4 replaced/48 dispensed)=7.7%
Other (e.g. damaged) (4/4)=100.0%

C. Clinical Data (Control Group)

Accountability (24 eyes enrolled): 24 completed

Visual Acuity:	Initial Visit with Lens	Final Visit with Lens
20/30 or better	21	22
20/40 or worse	3	2

Wear Time:	Initial	Final (1 month)
Daily	13.3 hours	12.9 hours

Adverse Reactions: None reported for all eyes enrolled

Slit Lamp Findings*:	Initial Visit (45/24 eyes)=187.5%	Final Visit (41/24 eyes)=170.8%
Neovascularization	16	16
Staining	19	17
Injection	2	0
Tarsal Abnormalities	8	8

*Multiple Findings Reported

Symptoms, Problems, Complaints: (26 reports/72 exams) = 36.1%
Categories reported=10

Vision Related (e.g. blurred, variable vision)	(4/26) = 15.4%
Comfort (e.g. discomfort, itching)	(19/26) = 73.1%
Other (e.g., lens needs cleaning)	(3/26) = 11.5%

Lens Replacements:	(3 replaced/24 dispensed) = 11.1%
Other (e.g. damaged)	(3/3) = 100%

V. Conclusion

The Center for Devices and Radiological Health (CDRH) reviewed the PMA and concluded that the PMA contained sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the device for the prescribed indications for use. This PMA was not referred to the Ophthalmic Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA submission duplicated information previously reviewed by that panel. CDRH approved this PMA in a letter to the applicant dated JAN 31 1997 and signed by the Director, Office of Device Evaluation.

PLEASE READ CAREFULLY AND KEEP THIS PACKAGE INSERT FOR FUTURE USE IN CASE YOU HAVE A PROBLEM.

Unizyme™
Enzymatic Cleaner

DESCRIPTION: Unizyme Enzymatic Cleaner is a tablet containing the enzyme subtilisin A, potassium carbonate, citric acid, polyethylene glycol and sodium benzoate.

ACTIONS: After a period of wearing, your contact lenses may develop a film on the lens surface caused by protein and other deposits from tears. Unizyme Enzymatic Cleaner contains an enzyme that breaks up proteins to facilitate their removal.

INDICATIONS (Uses): Unizyme Enzymatic Cleaner is indicated for use with chemical (including hydrogen peroxide) lens care systems in the weekly cleaning of soft (hydrophylic) contact lenses (including daily wear, extended wear, tinted lenses and lenses prescribed for scheduled replacement).

CONTRAINDICATIONS (Reasons not to use): If you are allergic to any ingredient in this product, do not use.

WARNINGS: PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE. It is essential that you follow your eye care practitioner's directions and all labeling instructions for proper use of your lenses and lens care products, including the lens case. EYE PROBLEMS, INCLUDING CORNEAL ULCERS, CAN DEVELOP RAPIDLY AND LEAD TO LOSS OF VISION.

Daily wear lenses are not indicated for overnight wear and should not be worn while sleeping. Clinical studies have shown the risk of serious adverse reactions is increased when these lenses are worn overnight.

Extended wear lenses should be regularly removed for cleaning and disinfection or for disposal and replacement on the schedule prescribed by your eye care practitioner. Clinical studies have shown that there is an increased incidence of serious adverse reactions in extended wear contact lens users as compared to daily wear contact lens users. Studies have also shown that the risk of serious adverse reactions increases the longer extended wear lenses are worn before removal for cleaning and disinfection or for disposal and replacement.

Studies have also shown that smokers have a higher incidence of adverse reactions.

IF YOU EXPERIENCE EYE DISCOMFORT, EXCESSIVE TEARING, VISION CHANGES, REDNESS OF THE EYE, IMMEDIATELY REMOVE YOUR LENSES AND PROMPTLY CONTACT YOUR EYE CARE PRACTITIONER.

All contact lens wearers should see their eye care practitioner as directed.

PRECAUTIONS:
- Use SoftWear® Saline, Pure Eyes™ Cleaner/Rinse, Quick CARE® Finishing Solution or a sterile saline solution (as recommended by your eye care practitioner) with the Unizyme tablets to prepare the cleaning solution.
- Distilled water and tap water are non-sterile. To help prevent contamination, DO NOT use these products to dissolve enzyme tablet.
- Use only freshly prepared enzymatic solution and discard immediately after use.
- Do not soak lenses in enzymatic solution for more than 12 hours.
- LENSES SHOULD NEVER BE PLACED ON THE EYE DIRECTLY FROM THE ENZYMATIC CLEANING SOLUTION AS SEVERE IRRITATION, BURNING AND STINGING MAY RESULT..
- DO NOT PUT ENZYMATIC CLEANING SOLUTION DIRECTLY INTO THE EYE AS SEVERE IRRITATION, BURNING AND STINGING MAY RESULT.
- Enzymatic cleaning is NOT a substitute for daily cleaning or disinfecting of your lenses. After enzymatic cleaning, lenses must be cleaned, rinsed and disinfected in the usual way prior to insertion. Failure to do so may result in eye irritation, burning or stinging.
- Tablets are not to be taken internally.
- Keep out of the reach of children. If accidentally swallowed conult your physician immediately.
- DO NOT use tablets that are discolored.
- DO NOT use tablets from packages that are torn or punctured.
- Use before expiration date marked on the carton and foil wrapper.
- Store at room temperature (15° to 30°C/59° to 86°F). Avoid excessive heat.

ADVERSE REACTIONS (Problems and what to do): The following problems may occur: eyes sting, burn or itch (irritation), comfort is less than when lens was first placed on the eye (foreign body, scratched area), feeling of something in the eye (foreign body, scratched area), excessive watering (tearing) of the eye, unusual eye secretions, redness of the eyes, reduced sharpness of vision (poor visual acuity), blurred vision, rainbows or halos around objects, sensitivity to light (photophobia) or dry eyes.

If you notice any of the above:
- IMMEDIATELY REMOVE YOUR LENSES.
- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, DO NOT put the lens back on your eye. Place the lens in the storage case and contact your eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign body on it, or the problems stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens, then reinsert it.
- If the problem continues, IMMEDIATELY remove the lens and consult your eye care practitioner.

If any of the above symptoms occur, a serious condition such as infection, corneal ulcer, neovascularization or iritis may be present. Seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage.

All adverse reactions observed while using Unizyme Enzymatic Cleaner should be reported to:

Consumer Relations
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30155

1-800-875-3001

GOOD LENS CARE PRACTICES:
- Always wash and rinse your hands before you handle your lenses. This will help to prevent eye infections by removing germs, dirt and oils that could get on the lenses.
- Clean, rinse and disinfect your lenses each time you remove them.
- Always handle the same lens, the right or the left, first in order to avoid mix-ups.
- After use, always empty and rinse the lens case with fresh rinsing solution and allow to air dry.
- Use only the solutions recommended by your eye care practitioner.
- Always follow the directions for use in the labeling included with each solution as instructions may be different for each solution.

DIRECTIONS FOR USE: See reverse side of this insert for detailed directions.

HOW SUPPLIED: Unizyme Enzymatic Cleaner is supplied in packages of 2 and 12 tablets. Tablets are sealed in foil and printed with a lot number and expiration date. Do not use if foil is open or damaged.

Manufactured for:
CIBA Vision Corporation
Duluth, Georgia 30155-1518

(month/year)
(Part Number)

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Unizyme™ *Enzymatic Cleaner*

- Regular enzymatic cleaning keeps lenses clear and comfortable.
- Unizyme Enzymatic Cleaner removes protein from your lenses in just 10 minutes.
- Use Unizyme Enzymatic Cleaner once a week or as recommended by your eye care practioner.
- Your lenses should be cleaned using the lens case included in your disinfection system.

Detailed Directions

AOSEPT® SYSTEM:

1 PREPARE YOUR LENS CUP
- Rinse the cup thoroughly and fill to the line with SoftWear® Saline or a sterile saline solution as recommended by your eye care practitioner.
- DO NOT USE ORDINARY TAP WATER OR DISTILLED WATER.
- Drop one Unizyme tablet in the lens cup. The solution will bubble as the enzyme dissolves.

2 ENZYME SOAK
- Wash and rinse your hands thoroughly before handling your lenses.
- After the enzyme tablet has completely dissolved, remove lenses from eyes and place them in the lens cup.
- Close lens cup and shake gently to ensure thorough mixing.
- SOAK LENSES FOR AT LEAST 10 MINUTES.
- If needed, lenses may be soaked overnight. Do not soak lenses in Unizyme solution for more than 12 hours.

3 CLEAN AND DISINFECT
- YOU MUST CLEAN AND DISINFECT YOUR LENSES AS A SEPARATE STEP FOLLOWING THE ENZYME TREATMENT.
- Remove lenses from lens cup.
- Pour out remaining Unizyme solution and rinse lens cup thoroughly with SoftWear Saline or a sterile saline solution as recommended by your eye care practitioner.
- Clean & disinfect lenses according to the AOSEPT patient instructions.
- Your lenses are now ready to wear.

PURE EYES™ SYSTEM:

1 PREPARE YOUR LENS CASE
- Rinse the case thoroughly and fill to the line with Pure Eyes Cleaner/Rinse or a sterile saline solution as recommended by your eye care practitioner.
- DO NOT USE ORDINARY TAP WATER OR DISTILLED WATER.
- Drop one Unizyme tablet in the lens case. The solution will bubble as the enzyme dissolves.

2 ENZYME SOAK
- Wash and rinse your hands thoroughly before handling your lenses.
- After the enzyme tablet has completely dissolved, remove lenses from eyes and place them in the lens case.
- Close lens case and shake gently to ensure thorough mixing.
- SOAK LENSES FOR AT LEAST 10 MINUTES.
- If needed, lenses may be soaked overnight. Do not soak lenses in Unizyme solution for more than 12 hours.

3 CLEAN AND DISINFECT
- YOU MUST CLEAN AND DISINFECT YOUR LENSES AS A SEPARATE STEP FOLLOWING THE ENZYME TREATMENT.
- Remove lenses from lens case.
- Pour out remaining Unizyme solution and rinse lens case thoroughly with Pure Eyes Cleaner/Rinse or a sterile saline solution as recommended by your eye care practitioner.
- Clean & disinfect lenses according to the Pure Eyes patient instructions.
- Your lenses are now ready to wear.

QUICK CARE® SYSTEM:

1 PREPARE YOUR LENS CASE
- Rinse the case thoroughly and fill with Quick CARE Finishing Solution or a sterile solution as recommended by your eye care practitioner.
- DO NOT USE ORDINARY TAP WATER OR DISTILLED WATER.
- Break one Unizyme tablet in half along the line, and place one half of the tablet in each side of the lens case. The solution will bubble as the enzyme dissolves.

2 ENZYME SOAK
- Wash and rinse your hands thoroughly before handling your lenses.
- After the enzyme tablet has completely dissolved, remove lenses from eyes and place them in the lens case.
- Close lens case and shake gently to ensure thorough mixing.
- SOAK LENSES FOR AT LEAST 10 MINUTES.
- If needed, lenses may be soaked overnight. Do not soak lenses in Unizyme solution for more than 12 hours.

3 CLEAN AND DISINFECT
- YOU MUST CLEAN AND DISINFECT YOUR LENSES AS A SEPARATE STEP FOLLOWING THE ENZYME TREATMENT.
- Remove lenses from lens case.
- Pour out remaining Unizyme solution and rinse lens case thoroughly with Quick CARE Finishing Solution or a sterile saline solution as recommended by your eye care practitioner.
- Clean & disinfect lenses according to the Quick CARE patient instructions.
- Your lenses are now ready to wear.

PLEASE SEE OTHER SIDE FOR MORE IMPORTANT INFORMATION.